DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 11, 2015

Mighty Oak Medical, Incorporated
Mr. Mark A. Wylie
Director of Quality
750 West Hampden Avenue, Suite 120
Englewood, Colorado 80110

Re: K143222
Trade/Device Name: FIREFLY™ Pedicle Screw Navigation Guide
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI
Dated: November 6, 2015
Received: November 9, 2015

Dear Mr. Wylie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143222

Device Name
FIREFLY™ Pedicle Screw Navigation Guide

Indications for Use *(Describe)*
The FIREFLY™ Pedicle Screw Navigation Guide is a patient-specific system intended to guide the drilling and tapping of pilot holes for placement of pedicle screws according to surgeon-prescribed pre-operatively planned trajectories during open, posterior, instrumented spinal surgery (T1-S1/Ilium). The FIREFLY™ Pedicle Screw Navigation Guide is intended for use with the pedicle screw spinal systems specified in the instructions for use and in patients consistent with the selected system's cleared indications for use.

Use of the FIREFLY™ Pedicle Screw Navigation Guide involves surgical planning software used pre-operatively to plan the surgical placement of the pilot holes on the basis of patient CT radiological images with identifiable placement of anatomical landmarks. Only compatible OEM taps that are supplied with the pedicle screw spinal systems specified in the instructions for use may be used through the FIREFLY™ Pedicle Screw Navigation Guide to tap pilot holes. All other pedicle screw spinal system components and accessories (including non-guided taps) are to be used after removal of the FIREFLY™ Pedicle Screw Navigation Guide, as directed by the pedicle screw spinal system's instructions for use.

This device is intended for single use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 8 – 510(k) Summary

Date:	December 8, 2015
Sponsor:	Mighty Oak Medical, Inc. 750 W. Hampden Ave., Suite 120 Englewood, CO 80110 (720) 398-9703
Contact Person:	Mark A. Wylie, Director of Quality
Trade Name:	FIREFLY™ Pedicle Screw Navigation Guide
Common Name:	Pedicle Screw Placement Guide
Device Classification:	Class II
Regulation, Name:	888.3070, Pedicle screw spinal system
Device Product Code:	MNI
Device Description:	The FIREFLY™ Pedicle Screw Navigation Guide is a patient-specific system intended to assist in the accurate placement of pedicle screws. It consists of single-use components designed for treatment of a specific patient as well as reusable non-patient-specific components. The FIREFLY™ Pedicle Screw Navigation Guide uses Patient-Specific Pedicle Screw Guides that fit on the patient's anatomy to guide surgical instruments in line with trajectories chosen presurgically, by the surgeon, based on the patient's CT imaging data. Navigation guides are intended to guide instruments to create pilot holes in the pedicles for placing pedicle screws following the Approved Patient-Specific Surgical Plan. Patient-Specific Bone Models may also be provided.
Intended Use:	The FIREFLY Pedicle Screw Navigation Guide is a patient-specific system intended to guide the drilling and tapping of pilot holes for placement of pedicle screws according to surgeon-prescribed pre-operatively planned trajectories during open, posterior, instrumented spinal surgery (T1-S1/Ilium). The FIREFLY™ Pedicle Screw Navigation Guide is intended for use with the pedicle screw spinal systems specified in the instructions for use and in patients consistent with the selected system's cleared indications for use. Use of the FIREFLY™ Pedicle Screw Navigation Guide involves surgical planning software used pre-operatively to plan the surgical placement of the pilot holes on the basis of patient CT radiological images with identifiable placement of

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anatomical landmarks. Only compatible OEM taps that are supplied with the pedicle screw spinal systems specified in the instructions for use may be used through the FIREFLY™ Pedicle Screw Navigation Guide to tap pilot holes. All other pedicle screw spinal system components and accessories (including non-guided taps) are to be used after removal of the FIREFLY™ Pedicle Screw Navigation Guide, as directed by the pedicle screw spinal system's instructions for use.

This device is intended for single use only.

Materials: The patient-contacting components of the FIREFLY™ Pedicle Screw Navigation Guide are manufactured from titanium alloy (ASTM F136), various stainless steels (ASTM F899), and epoxy resin (Accura ABS White SL 7810).

Predicate Devices: Primary:
MySpine Pedicle Screw Placement Guides (Medacta International SA: K132788)

Reference:
VSP® System (3D Systems [formerly Medical Modeling Inc.]: K120956 and K133907),
TRUMATCH Personalized Solutions (DePuy Synthes: K110397)

Performance Data: Cadaveric accuracy and sterilization stability testing of the FIREFLY Pedicle Screw Navigation Guide was performed. The results demonstrated that the acceptance criteria were met and that the FIREFLY Pedicle Screw Navigation Guide performance is adequate to perform as intended.

Technological Characteristics: The FIREFLY Pedicle Screw Navigation Guide possesses the same technological characteristics as the predicate devices. These include:

- performance,
- manufacturing process,
- biocompatible materials, and
- basic design.

Technological characteristics which are different have been supported with descriptive information and/or performance data. Therefore the fundamental scientific technology of the System devices is the same as previously cleared devices.

Conclusion: The FIREFLY Pedicle Screw Navigation Guide possesses the same intended use and technological characteristics as the predicate devices. Therefore the FIREFLY Pedicle Screw Navigation Guide is substantially equivalent for its intended use.